

### **REMARKS/ARGUMENTS**

The present amendment is in response to the final Office Action mailed June 15, 2004, in which Claims 1 through 10, 12 and 14 through 18 were rejected. Applicants have thoroughly reviewed the outstanding Office Action including the Examiner's remarks and the reference cited therein. The following remarks are believed to be fully responsive to the Office Action and are believed to render all claims at issue patentably distinguishable over the cited references.

No claim is amended herein. No claim is cancelled. No claim is added. Accordingly, Claims 1 through 10, 12 and 14 through 18 remain pending.

Applicants respectfully request reconsideration in light of the following remarks

### **CLAIM REJECTIONS - 35 U.S.C. SECTION 103(a)**

The Examiner rejected Claims 1 through 10 and 12, and 14 through 18 under 35 U.S.C. Section 103(a) as being unpatentable over:

- EP 148600 or Thomas *et al.* in view of Satoh *et al.* and further in view of Chigurapati *et al.* or Olsen;
- Chiguarapati *et al.* or Olsen taken with Satoh *et al.*
- Dalbøge *et al.* Edens *et al.*, or Schoenmaker *et al.* in view of Satoh *et al.*

Applicants respectfully traverse these rejections.

## **The Invention - In Brief**

Briefly, the whole process claimed in the present application is set up in such a way that 10.5-11.0% nitrogen is obtained in the product. The final product obtained by the above process would have 10.5-11.0% nitrogen, 20 – 23 trypsin inhibitor units/ mg protein, 95 – 98% nitrogen solubility index, 2 – 2.2% bitterness recognition threshold and 35 – 45% degree of hydrolysis. The cream colored product further has no detectable lipoxygenase or urease activities and has a similar amino acid make up as the starting material.

## **EP 148600**

The reference EP148600 relates to the preparation of hydrolyzed protein from protein isolate. The solubility profile of the protein of EP 148600 depends upon the net charge distribution and size of the protein and protein isolate, which is soluble in water and is not soluble at pH 4.5. Similarly, any pretreatment like jet cooking or dynamic as done by EP changes the conformation of the protein completely and the properties of the substrate. The proteins would thus become more susceptible to cleavage by proteolytic enzymes compared to the present invention. Further, heating of the proteins could also result in a change in the nutritional profile as amino acid content. In the current invention, the amino acid profile of the product is the same as the starting material.

The cleavage of protein by papain would depend on the conformation of the protein which decides the extent of exposure of the peptide bond. The

exposure of peptide bond for cleavage by any proteolytic enzyme is dependent on :

- a) Conformation of the protein
- b) Charge distribution on the surface of the protein.

The selection of the right kind of pH, temperature, enzyme to substrate ratio, conformation of the substrate to give the final desired product in the present invention is not obvious. The process parameters that have been used ensure the desired conformation of the protein and the desired charge distribution on the surface of the protein. No other combination of steps or process would give the product described in the process.

**Thomas *et al.***

Thomas *et al.* teach the preparation of soy protein concentrate using carbohydrate splitting enzymes like pectinases, phytase and a nuclease. These enzymes are different from proteases and do not split the protein component at all. Thus, the soy protein remains intact. In the present invention, the soy protein is degraded to smaller components (peptides) and the degree of hydrolysis is 35 – 45%.

**Satoh *et al.***

Satoh *et al.* teach a process for obtaining two kinds of hydrolyzed proteins by hydrolyzing soy protein with protease and separating the mixture of

hydrolyzed products. However, both the process and the product differ substantially from the process and product of the present invention. Specifically, Satoh *et al.* use their solubilities in a 5% trichloro acetic acid (TCA) aqueous solution as the guidance of the separation. This process has nothing to do with the present invention. This is understandable insofar as the process is directed to the production of *two* products using the TCA solubilization by weight - one finding utility as an emulsifying agent, the other finding use as a foaming agent. In fact, it is clear that not only does the Satoh *et al.* reference fail to teach, suggest or otherwise render the claimed invention obvious, but it actually teaches away from the present invention.

#### **Chigurapati *et al.***

Chigurapathy *et al.* claim a method for producing a savory flavor base and the process involves fermentation. Fermentation relates to a number of changes brought about to the substrate including the carbohydrate, fat and protein component. The present invention is only bringing about change in the protein component of the substrate and this is done enzymatically.

#### **Olsen**

The patent to Olsen teaches a method of producing an egg white substitute material from soy protein. More specifically, Olsen teaches enzymatic hydrolysis, however, the described method results in a degree of hydrolysis of only 6% which teaches away from the invention as presently claimed.

**Dalbøge *et al.***

The patent to Dalbøge *et al.* teaches a DNA construct which encodes an enzyme with protease activity, the method of producing such a construct, and an enzyme preparation containing the enzyme. The enzyme of the invention is active at a pH below 7.0. As applying to the present invention, Dalbøge *et al.* teaches only a protease having an activity range specifically different from that claimed in the present invention. Like Satoh *et al.*, Dalbøge *et al.* teach away from the invention as claimed.

**Edens *et al.***

The patent to Edens *et al.* teach a specific method for producing a protein hydrolysate. Particularly, Edens *et al.* narrowly teach the use of essentially a single exopeptidase, in conjunction with one or more endopeptidase to prepare the protein hydrolysate. While this reference gives great attention to the particular exopeptidase, it is not useful in teaching, suggesting or otherwise rendering obvious Applicants' particular process, particularly with respect to the second hydrolyzation of the slurry and the resulting hydrolysates.

**Schoenmaker *et al.***

Schoenmaker *et al.* relates to a process for producing a flavor enhancer. The process specifies five steps: (1) forming an aqueous suspension of a soy protein; (2) heating the aqueous suspension "for at least from about 1 minute to

about 15 minutes at a temperature of from about 60° C. to about 82° C."; (3) incubating the suspension with a protease mixture having endoprotease and exoprotease activity; (4) adjusting the pH and temperature of the suspension; and (5) recovering the soy protein hydrolysate. This methodology is quite different from that presently claimed which includes at least the differences of time ranges, different temperature ranges, and the number of hydrolyzations. Schoenmaker *et al.* does little to provide instruction regarding the invention as claimed.

#### **Combination Of These References As The Bases For Rejection**

Applicants respectfully submit that it is clear from the excessive number of references cited that the Examiner, having failed to find "obviousness" in one or two citations, is attempting to extract bits and pieces from a number of individual patents so as to re-assemble, with the benefit of hindsight, the present invention. But the Examiner's use of hindsight in an effort to reconstruct Applicants' process is clearly not permitted, and the CAFC has recently reinforced its opposition to such measures. In *Beckson Marine Inc. v. NFM Inc.*, 292 F.3d 718, 63 USPQ2d 1031 (Fed. Cir. 2002), the Court stated:

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the [challenger] to show a motivation to combine the references that create the case of obviousness. In other words, the artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

Please also see *In re Thrift*, 298 F.3d 1357, 63 USPQ2d 2002 (Fed. Cir. 2002), *In re Huston*, 308 F.3d 1267, 64 USPQ2d 1801 (Fed. Cir. 2002), and *Akamai Technologies Inc. v. Cable & Wireless Internet Services Inc.*, 68 USPQ2d 1186, 344 F.3d 1186 (Fed. Cir. 2003)

It is clear that there is no motivation to combine these references in the manner undertaken by the Examiner. Applicants respectfully ask, where, for example, is the motivation to combine the DNA construct teachings of Dalbøge *et al.* with the process of Satoh *et al.* to produce the latter's emulsifying and foaming agents? In answering this question, it is critical to keep in mind that the motivation to combine references must be clear and particular and, as recently reaffirmed by the CAFC, the motivation to combine references *must be supported by actual evidence*. *Teleflex Inc. v. Ficosa North America Corp.*, 63 USPQ2d 1374 (CAFC 2002), quoting *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). Applicants respectfully submit that there is no actual evidence to support the Examiner's combination and that there is no motivation to combine these references.

Motivation to combine these references depends on the desirability of such a combination and not on whether or not the references *can* be combined or modified - there must be a showing the *desirability* of the combination, and the suggestion or motivation to make such a combination must *be in the reference*. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990). This requirement cannot be dispensed with:

"Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous

application of the requirement for a showing of the teaching or motivation to combine prior art references." *In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

Applicants respectfully submit that the proposed combinations of (1) EP 148600 or Thomas *et al.* in view of Satoh *et al.* and further in view of Chigurapati *et al.* or Olsen, (2) Chigurapati *et al.* or Olsen taken with Satoh *et al.*, or (3) Dalbøge *et al.* Edens *et al.*, or Schoenmaker *et al.* in view of Satoh *et al.* are not suggested in any way in the references and that there is no evidence to support such a combination.

### **The Resulting Combinations**

Even if evidence of motivation for making such combinations were identified and that the proposed combinations were legitimate, Applicants respectfully submit that the resulting combinations would still fail to render obvious the present invention as claimed.

Examples of *possible* literal resulting processes from these combinations appear hereafter. These examples are not comprehensive but are used to illustrate how the proposed combinations fail to render the present invention obvious and, in fact, at least partially teach away from the invention as claimed.

The combination of EP 148600 or Thomas *et al.* in view of Satoh *et al.* and further in view of Chigurapati *et al.* or Olsen would somehow result in *either* a hydrolyzation process that results in two possible cleaved proteins, one having utility as an emulsifying agent, the other as a foaming agent with the process relying upon fermentation if relying upon EP 148600, *or*, if relying upon Thomas



*et al.*, a hydrolyzation process that results in intact soy proteins, one having utility as an emulsifying agent, the other as a foaming agent.

The combination of Chiguarapati *et al.* or Olsen taken with Satoh *et al.* would somehow result in a process creating *either* two products, one having utility as an emulsifying agent, the other as a foaming agent, through fermentation if relying upon Chiguarapati *et al.*, *or*, if relying upon Olsen, in a process that creates two products, one having utility as an emulsifying agent, the other as a foaming agent, in either event having a degree of hydrolysis of only 6%.

The combination of Dalbøge *et al.*, Edens *et al.*, or Schoenmaker *et al.* in view of Satoh *et al.* would result possibly in a process for the production of a DNA construct (if relying upon Dalbøge *et al.*) in two forms, one having utility as an emulsifying agent, the other as a foaming agent, *or*, a process for preparing a protein hydrolysate dependent upon a single exopeptidase, the process resulting in a product having two forms, one having utility as an emulsifying agent, the other as a foaming agent, *or*, a process for preparing a flavor enhancer with only a single step of exposure to a protease resulting in a product having two forms, one having utility as an emulsifying agent, the other as a foaming agent.

In any event, Applicants respectfully submit that the resulting combinations do not teach, suggest, or otherwise render obvious the invention as presently claimed.

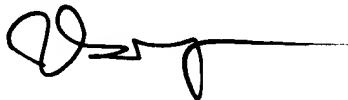
Reconsideration and withdrawal of the rejections under 35 U.S.C. Section 103(a) are respectfully requested.

### CONCLUSION

In light of the above remarks, Applicants respectfully submit that all pending Claims 1 through 10, 12 and 14 through 18 as currently presented are in condition for allowance. If, for any reason, the Examiner disagrees, please call the undersigned attorney at 248-433-7552 in an effort to resolve any matter still outstanding *before* issuing another action. The undersigned attorney is confident that any issue which might remain can readily be worked out by telephone.

Applicants respectfully request that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'T. Moga', followed by a long horizontal line extending to the right.

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